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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/638,393	08/12/2003	Ming-Hsiung Yeh	P-6144	5466
26253	7590	08/21/2006		
DAVID W. HIGHET, VP AND CHIEF IP COUNSEL BECTON, DICKINSON AND COMPANY 1 BECTON DRIVE, MC 110 FRANKLIN LAKES, NJ 07417-1880			EXAMINER GAKH, YELENA G	
			ART UNIT 1743	PAPER NUMBER

DATE MAILED: 08/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/638,393	YEH ET AL.	
	Examiner	Art Unit	
	Yelena G. Gakh, Ph.D.	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 July 2006.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-28 is/are pending in the application.
 4a) Of the above claim(s) 19-28 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-18 is/are rejected.
 7) Claim(s) 6 and 18 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 12 August 2003 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>01/27/05</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. Election of claims 1-18 without traverse filed on 07/10/06 is acknowledged. Claims 19-28 are withdrawn from consideration.

Claim Objections

2. Claims 6 and 18 are objected to because of the following informalities: claim 6 recites “tris-1,7-diphenyl” instead of “tris-4,7-diphenyl” in the ruthenium salt name. Claim 18 recites a non-existing compound “polyethylene glucose”. PEG is a conventional abbreviation for “polyethylene glycol”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1-2 and 7-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recite “a core comprising at least one oxygen-sensing particle”. A huge variety of oxygen-sensing compounds are known, including organic and inorganic compounds, such as metals, metal oxides, carbons, fluorophores, etc.. “Oxygen-sensing particle” is an indefinite term, since it is not even apparent whether the particle belongs to the class of organic or inorganic compounds, which renders claims 1-2 and 7-18 unclear and indefinite.

Claim 10 recites “a carrier molecule”. What may be “a carrier molecule”? What specifically does it carry? Does it carry the particle? Should it be a polymer, which can carry the particle? The term “a carrier molecule” is unclear and indefinite.

Also, it is not clear, what is the difference between the core portion and the hydrophobic coating, if both, the core and the coating comprise the same compound, such as polystyrene?

From claim 12 it is not clear, what is the difference between the hydrophobic coating and additional coating, especially if additional coating is a hydrophobic coating, as recited in claim

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13? Since it appears to be the same hydrophobic coating, the examiner considers the recitation of claim 12 enclosing an embodiment, in which both coatings are the same substance.

In claim 14 it is completely unclear as to what is meant by term “matrix”. “Matrix” is a very general term, which has a variety of different meanings. It is completely unclear, what “matrix” may be in the context of claim 14. Moreover, it is not clear, if the matrix is separated from the core and the coating, is a part of the coating, a part of the core, etc. The examiner considers matrix as a part of the coating.

From claim 15 it is completely unclear as to how the composition of claim 1 is related to cell culturing.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1-4, 7-14** are rejected under 35 U.S.C. 102(b) as being anticipated by McDonagh et al. (Sensors and Actuators, 2001) as evidenced by McDonagh in Anal Chem., 1998.

McDonagh teaches a “phase fluorometric dissolved oxygen sensor”, comprising “an oxygen-sensitive ruthenium complex” as a core particle. “The complex is entrapped in a porous hydrophobic sol-gel matrix that has been optimized for this application. The LED excitation and photodiode detection are employed in a dipstick probe configuration, with the oxygen-sensitive film coated on a disposable PMMA disk” (Abstract). The ruthenium complex is $[\text{Ru}^{\text{II}}\text{-Tris}(4,7\text{-diphenyl-1,10-phenanthroline})]^{2+}$, $(\text{Ru-(Ph}_2\text{phen})_3)^{2+}$ ” (page 124, left column). While McDonagh in Sensors and Actuators does not specify the nature of sol-gels, in his article in Analytical Chemistry he indicates that “organically modified sol-gel precursors such as methyltriethoxysilane and ethyltriethoxysilane” are transformed into sol-gel by hydrolysis and condensation polymerization (see page 45, left column).

7. **Claims 1-4, 6-18** are rejected under 35 U.S.C. 102(e) as being anticipated by Xu et al. (Anal. Chem., 2001).

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Xu teaches using “sol-gel-based spherical optical nanosensors with applications to rat C6 glioma” (Title), comprising Ru(II)-tris(4,7-diphenyl-1,10-phenanthroline) chloride. Sol-gels are polymers obtained by hydrolysis and condensation polymerization reaction of the same derivatized silicates as indicated by McDonagh. The sol-gel PEBBLES are improved by addition of PEG, which acts as a steric stabilizer and reduces the particle diameter to about 0.1-1.5 μm , which facilitates their transport. “The addition of PEG to the sensing matrix also greatly helped improve the sensor performance in oxygenated water” (page 4127, right column).

8. **Claims 1-8** are rejected under 35 U.S.C. 102(e) as being anticipated by Stitt et al. (WO 98/12348).

Stitt teaches a composition for microbial monitoring device based on oxygen sensing with the core particle comprising fluorescent compounds, in particular “tris-2,2'-bipyridyl ruthenium (II) salts, especially the chloride hexahydrate salt ($\text{Ru}(\text{BiPy})_3\text{Cl}_2$), tris-4,7-diphenyl-1,10-phenanthroline ruthenium (II) salts, especially the chloride (salt ($\text{Ru}(\text{DPP})_3\text{Cl}_2$) and 9,10-dupghenyl anthracene (DPA)” (page 7). The fluorescent indicator compound is embedded in the silicone rubber (see e.g. page 12).

9. **Claims 1 and 7** are rejected under 35 U.S.C. 102(e) as being anticipated by He et al. (Proc. Intl. Soc. Mag. Reson. Med., 2001, Phys. Med. Biol., 2001).

He discloses hydrophobic “coating of oxygen sensitive paramagnetic particles for EPR oximetry” and “microencapsulation of carbon particles used as oxygen sensors in EPR oximetry to stabilize their responsiveness to oxygen *in vitro* and *in vivo*” (Titles), with the coating comprising different biopolymers, such as cellulose nitrate, cellulose acetate, polyurethane and silicone.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Xu in view of Stitt et al. (WO 98/12348).

While Xu does not specifically disclose a different Ru (II) complex, i.e. tris-2,2'-bipyridyl-ruthenium (II) chloride hexahydrate, Stitt teaches a composition for microbial monitoring device based on oxygen sensing with the core particle comprising fluorescent compounds, in particular “tris-2,2'-bipyridyl ruthenium (II) salts, especially the chloride hexahydrate salt ($\text{Ru}(\text{BiPy})_3\text{Cl}_2$), tris-4,7-diphenyl-1,10-phenanthroline ruthenium (II) salts, especially the chloride (salt ($\text{Ru}(\text{DPP})_3\text{Cl}_2$) and 9,10-dupghenyl anthracene (DPA)” (page 7).

It would have been obvious for any person of ordinary skill in the art to use tris-2,2'-bipyridyl ruthenium (II) indicated by Stitt instead of $(\text{Ru}-(\text{Ph}_2\text{phen}))_3^{2+}$, disclosed by Xu, because it is another very effective fluorescent Ru(II) complex with similar properties to the one disclosed by Xu.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

8/16/06



YELENA GAKH
PRIMARY EXAMINER